



REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 07/25/2016

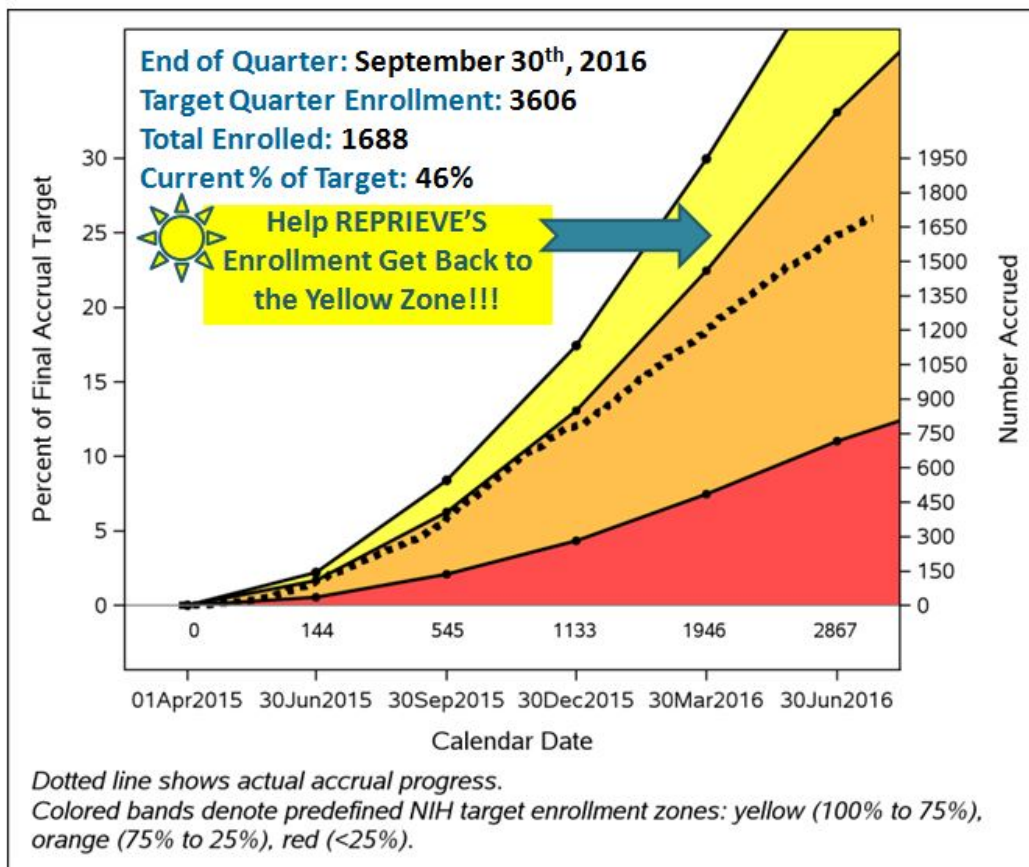
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Enrollment Updates

Thank you to every site enrolling participants in REPRIEVE, with your help **we have enrolled 1688 participants, 19 participants were enrolled last week! 177 participants are in screening and we now have 90 sites open for enrollment.**

To bring us closer to our target enrollment, at least 50 participants need to be enrolled each week. With 90 sites activated, this is possible! If 50 participants are enrolled each week, our enrollment will be over 2,000 in close to 6 weeks!!!



Thank you to all sites enrolling participants week of 07/18/2016

- Thai Red Cross AIDS Research Center
- UCSD Antiviral Research Center CRS
- Penn Therapeutics CRS
- Cincinnati CRS
- University of Rochester Adult HIV Therapeutic Network CRS
- Trinity Health and Wellness Center
- Massachusetts General Hospital (MGH) CRS
- Rush University CRS
- Florida Department of Health
- Cooper University Hospital
- Mount Sinai Clinical and Translational Research Center
- Mt Sinai St Lukes Samuels Clinic
- Michael D. DeBakey VAMC
- Drexel University
- University of Iowa
- Oklahoma State University Center for Health Sciences CRS



I am in the process of contacting candidates to re-screen for REPRIEVE. If an individual is interested, how do I proceed?

If a candidate re-screens for REPRIEVE there are a few things to remember.

You can use the same screening number if you are still able to enroll the participant within 90 days from when the screening number was first assigned.

However, you cannot have already completed the SCR0034--Screening Outcome form--with an indication that NO the participant will not enroll, this will block the screening number from being seen as 'eligible' when you submit the enrollment checklist.

If the screening number was generated more than 90 days from the time of enrollment, you should complete the checklist again.

When completing the checklist again, you will be prompted by the checklist to indicate if the participant had a previous screening number. Indicate they did, and enter the old screening number.

You will have to complete a SCR0034 – Screening Outcome form--for BOTH the screening number that was previously used (indicating they did not enroll) and the new screening number once it is determined if the participant will enroll or not.



Study Medication Reminders!

Have frequent conversations with your participants about their study participation:

- Remind your participants that they are on pitavastatin or placebo and that pitavastatin is a statin medication.
- Advise participants that if another provider (i.e. during hospitalization, primary care) wants to start a statin medication, have the provider consult with the study team immediately. This way we can prevent inadvertent overdoses.
- **Best practice:** when you learn of a hospitalization, always review the discharge medications with the participant.

There is a [Participant Card](#) that you can download and give to your study participants. It can be used to alert other providers that the individual is participating in the REPRIEVE trial and they may be on a blinded statin. The card is attached [here](#) and can be found on the REPRIEVE PSWP (go to *Protocol Training > Optional Tools* folder).*

*This has been approved by the IRB for the REPRIEVE CCC, however, please submit to your local IRB as per your local IRB policies.



What's New on the REPRIEVE PSWP?

The Prohibited and Precautionary Medication List has been updated and is attached [here](#). Updates include:

- Instruction regarding statin use during study participation.
 - Please note: Participants who begin therapy with a statin other than the study drug should discontinue study drug **until it is determined that there is a clinical indication for statin therapy. (For example, if statin is initiated short term during hospitalization by non-PCP for an unclear indication and can be stopped, resumption of study drug is permissible). If statin therapy must be continued for clinical reasons and participant remains on statin therapy not provided by the study,** the participant should be followed **on study**/off study treatment through the study termination visit with evaluations per protocol.
- All Directly Acting Antiviral Agents for HCV are considered Precautionary Concomitant Agents
 - Instructions have been updated in this category.

In the Protocol Training folder we have added a tool called [Adjudicated Events Terminology](#). These are descriptive terms for REPRIEVE adjudicated events and may be helpful when completing the Adjudicated Event Tracking CRF.



Tools You Can Use!

After our Site Call this past Tuesday, 3 sites shared tools* they developed to schedule visits. Each tool is unique but gets to the same goal: an accurate way to calculate future visits!

Rachelle Price, MPH from Northwestern University, Site 2701 shared the [tool](#) her site developed. She prints a copy for the source documents for the study nurses and she has a binder of participant calendars to track visits. Before printing, she hides Column B so the formulas don't show.

Ilene Wiggins, RN from Johns Hopkins University, Site 201, also shared her [calendar template](#). This template calculates the visit windows which is very useful for when scheduling visits. When a participant enrolls in REPRIEVE the template is made participant specific by adding the PID, SID, and date enrolled. Once the template is populated with participant-specific information, it is printed and placed in the participant's chart.

Alex Illes, MPH, CCRC from Positive Health Clinic, Site 31910, also shared her [Excel visit calculator](#). There are two sheets, one for the window between screen and entry and the visits.

We will keep these calculators on the REPRIEVE PSWP (go to *Protocol Training > Optional Tools* folder).*

Thank you Rachelle, Ilene, and Alex for sharing these tools with us!

If your site has developed a tool for REPRIEVE, please let us know so we can share it with other sites, email Katie Fitch, kfitch@partners.org.

*Please note these tools have not been vetted by the REPRIEVE team.



Important Message about Shipments to BRI

Are You Unable to Ship During Your Assigned Time?

If you anticipate that your site will be unable to ship during the assigned schedule (non-ACTG sites please see non-ACTG site shipping schedule [attached](#) and on the PSWP in Lab Resources), you must notify the repository (BRI) at brirepository@afbr-bri.com so that they are aware.

Prior to shipping, confirm with BRI that the week you are able to ship will work with their schedule. After this, your site should resume to its assigned schedule.

Only ship on Monday, Tuesday or Wednesday!

As a reminder, **shipments must be sent to BRI only on Mondays, Tuesdays, or Wednesdays**. BRI is closed during the weekend and they do not want to take a chance with delayed shipments arriving after Friday.



TRAINING OPPORTUNITIES

ECG Training Dates

Wednesday, 27 July, 10:00 AM ET

Thursday, 11 Aug, 10:00 AM ET

Thursday, 25 Aug, 10:00 AM ET

This 30-minute training webinar includes information on the ECG machine and supplies, performing the ECG, and transmission of data to Quintiles. This training is specific to the

REPRIEVE trial and at least one person from your site must attend one training to meet protocol activation requirements, although we encourage you to have all staff that will work with the Quintiles ECG machine to attend the training, eg, PI, study coordinator, CRA, backup personnel. If you need a refresher, please join!

Your site does *not* need to be DAIDS site activated or protocol registered, nor do you need to have your Site Qualification Form (SQF) signed or the ECG machine onsite to participate in this training.

If you have not received a calendar invite regarding ECG training and would like to attend please email Barbara Bastow at bbastow@s-3.com.

Protocol Training/ Start-Up Call Slides

Slides used for protocol training are kept in the Protocol Training Folder on the A5332 and A5333s protocol-specific pages (PSWPs). The PSWP is located in the Member portal of the [ACTG website](#).

The most recent A5332 training slides "Summer 2016" have been posted on the PSWP!

The Data Management Center, FSTRF, is developing some excellent videos for you to use!

Videos to address commonly asked questions will be posted to the FSTRF portal soon
Topics include:

- Missed Visit
- Out of Window Visit
- Changing Previously Saved Data
- Logs
- Unknown or Missing Data
- Notes and Discrepancies

A notification email and instructions on how to access these instructional videos will be sent soon, so stay tuned...

Web LDMS Training Videos

If you are a site using Web LDMS for REPRIEVE, check out the Web LDMS training videos available on [FSTRF's YouTube Channel](#).

These training videos are the same training(s) that FSTRF staff have been providing REPRIEVE laboratories. We encourage lab staff to watch these videos as a means of refresher training. Please share these links with laboratory staff at your sites if they do not receive the REPRIEVE newsletter.

Cardiovascular Care for the Patient Living With HIV: What You Need to Know

Merle Myerson, MD, EdD

[Disclosures](#) | July 07, 2016

Merle Myerson, MD, EdD recently published an informative article about cardiovascular care for people living with HIV on **Medscape**. [Click here to download.](#)

The article stresses the importance of trials such as REPRIEVE which will develop treatment guidelines specifically for people living with HIV.

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol:

Version 3.0 dated 01/28/2016

Clarification Memo #1 dated 04/04/2016

Clarification Memo #2 dated 04/12/2016 (corrects an error in CM #1)

MOPS:

Version 3.0, revision 1, dated 04/15/2016

A5332 LPC for ACTG Sites:

Version 3.0 dated 02/23/2016

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 05/05/2016

These documents are on the [A5332 PSWP](#)

REPRIEVE Mechanistic Substudy (A5333s): Are you up to date?

For A5333s please use

Protocol: *Version 3.0 dated 01/28/2016*

MOPS: *dated 11/10/2015*

A5333s LPC : *Version 3.0 dated 05/05/2016*

These documents are on the [A5333s PSWP](#)

For future reference, all newsletters are available on the [REPRIEVE Website](#)

We welcome suggestions and ideas for upcoming newsletters. Please submit any comments or

suggestions to the REPRIEVE News Team at reprieve.news@fstrf.org.



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